

THREE-YEAR OUTCOMES OF ASPIRATION-ASSISTED FOAM MECHANOCHEMICAL ABLATION FOR SAPHENOUS VEIN INSUFFICIENCY: A RETROSPECTIVE COMPARATIVE STUDY

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Abstract

Mechanochemical ablation (MOCA) is an established non-thermal treatment for saphenous vein insufficiency. However, long-term durability remains limited by recanalization. This study evaluated the long-term outcomes of aspiration-assisted foam MOCA compared with conventional MOCA and investigated factors associated with anatomical failure. This retrospective comparative cohort study included 220 consecutive patients with symptomatic great or small saphenous vein insufficiency. The first 110 patients underwent conventional MOCA using liquid polidocanol, whereas the subsequent 110 patients were treated with aspiration-assisted foam MOCA. All patients completed a 36-month clinical and duplex ultrasound follow-up. The primary endpoint was anatomical success, defined as complete vein occlusion without partial or complete recanalization. At 36 months, anatomical success was achieved in 83 of 110 patients (75.5%) treated with conventional MOCA and in 95 of 110 patients (86.4%) treated with aspiration-assisted foam MOCA. Recanalization occurred in 24.5% and 13.6% of patients, respectively. Both groups demonstrated significant clinical improvement. Preoperative vein diameter was strongly associated with anatomical failure, with recanalization rates increasing from 6.0% in veins measuring ≤ 8 mm to 83.3% in veins larger than 12 mm. Multivariate analysis identified preoperative vein diameter as the strongest independent predictor of recanalization (OR 1.87 per 1-mm increase, $p < 0.001$). Two cases of deep vein thrombosis and no cases of pulmonary embolism were observed. Aspiration-assisted foam MOCA was associated with higher anatomical success than conventional MOCA at 36 months. Preoperative vein diameter was

the most powerful predictor of recanalization and should be considered when selecting patients for mechanochemical ablation.

Key words: mechanochemical ablation, saphenous vein insufficiency, aspiration assisted MOCA, foam sclerotherapy, recanalization, vein diameter

Introduction. Chronic venous disease (CVD) is one of the most prevalent vascular disorders worldwide and is associated with substantial morbidity, impaired quality of life, and considerable healthcare costs [1, 2]. Incompetence of the great saphenous vein (GSV) and small saphenous vein (SSV) represents a major cause of symptomatic venous reflux and varicose vein formation [2]. During the last two decades, endovenous interventions have largely replaced conventional surgical stripping for the treatment of saphenous vein insufficiency [3]. Although endothermal techniques such as endovenous laser ablation and radiofrequency ablation demonstrate excellent long-term occlusion rates, they require tumescent anesthesia and may be associated with thermal injury, postoperative pain, and nerve damage [4, 5]. Mechanochemical ablation (MOCA) was developed as a non-thermal, non-tumescent alternative that combines mechanical disruption of the endothelium with the simultaneous administration of a sclerosant [6, 7]. Several studies have demonstrated favourable short- and mid-term outcomes, reduced postoperative discomfort, rapid recovery, and high patient satisfaction following MOCA [8–12]. However, long-term durability remains a concern, with recanalization rates generally exceeding those reported after thermal ablation [13–16]. One proposed mechanism of treatment failure is the presence of intraluminal blood, which may dilute the sclerosant and reduce its contact with the venous wall, thereby limiting endothelial destruction and promoting recanalization [17]. In addition, previous studies have suggested that larger vein diameter is associated with an increased risk of anatomical failure following mechanochemical ablation [8, 9]. To address these limitations, we developed an aspiration-assisted foam MOCA technique designed to reduce intraluminal blood volume during sclerosant administration and improve sclerosant-wall contact. The present study aimed to compare the three-year anatomical and clinical outcomes of aspiration-assisted foam MOCA with those of conventional MOCA in patients with saphenous vein insufficiency. A secondary objective was to identify factors associated with long-term anatomical failure, with particular emphasis on the influence of preoperative vein diameter.

Materials and methods. This retrospective single-centre cohort study included 220 consecutive patients with symptomatic GSV or SSV incompetence treated between January 2019 and December 2022. The first 110 patients underwent conventional MOCA and the subsequent 110 aspiration-assisted foam MOCA, using identical eligibility, assessment, and follow-up protocols. Eligible patients had duplex-confirmed saphenous reflux, CEAP class C2–C6, and completed 36-month follow-up. Previous target-vein treatment, deep venous obstruction, acute deep vein thrombosis, pregnancy, and incomplete follow-up were ex-

clusion criteria. Baseline assessment included CEAP class, VCSS, CIVIQ-20, vein type, and maximal vein diameter measured by standing duplex ultrasound. The study complied with the Declaration of Helsinki, and all patients provided written informed consent for treatment and use of anonymized data.

Procedure technique. All procedures were performed under ultrasound guidance using the ClariVein[®] system (Merit Medical, South Jordan, UT, USA), with the catheter positioned approximately 2 cm distal to the saphenofemoral or saphenopopliteal junction. In conventional MOCA, rotating-wire endothelial disruption was combined with approximately 8 mL of 1.5% liquid polidocanol (Fibrovein[®]) administered during catheter withdrawal. In aspiration-assisted MOCA, 1.5% polidocanol foam, prepared using the Tessari technique at a 1:4 sclerosant-to-air ratio, was delivered through the catheter during withdrawal, while continuous aspiration of the foam–blood mixture was performed through a 6F sheath using a 20-mL syringe. Concomitant ambulatory phlebectomy was performed when indicated. All patients received low-molecular-weight heparin (LMWH) before the procedure, as this was part of the standard protocol. The dose was adjusted according to the patient's body weight.

Postprocedural care and follow-up. Immediate ambulation and class II compression stockings for 14 days were recommended. Clinical and duplex ultrasound assessments, including CIVIQ-20 and VCSS scores, were performed at 1, 12, and 36 months. During the hospital stay, patients received LMWH for 3 days following the procedure. In selected cases, DOAC therapy was prescribed for one month based on the individual patient's clinical characteristics.

Study endpoints. The primary endpoint was anatomical success at 36 months, defined as complete occlusion of the treated vein without evidence of partial or complete recanalization on duplex ultrasound examination. Anatomical failure was defined as the presence of any recanalization, including both partial and complete recanalization. Secondary endpoints included changes in VCSS and CIVIQ-20 scores, patient satisfaction, and procedure-related complications, including hematoma, hyperpigmentation, superficial thrombophlebitis, deep vein thrombosis, and pulmonary embolism.

Statistical analysis. Continuous variables are presented as mean $\pm$ standard deviation and categorical variables as frequencies and percentages. Group comparisons used Student's *t*-test, Pearson's chi-square test, or Fisher's exact test, as appropriate. Statistical significance was set at $p < 0.05$. Analyses were performed using IBM SPSS Statistics.

Results. A total of 220 consecutive patients were included in the study. The first 110 patients underwent conventional MOCA, whereas the subsequent 110 patients were treated with aspiration-assisted MOCA. All patients completed the planned 36-month clinical and duplex ultrasound follow-up.

The mean age was 46.6 years in the conventional MOCA group and 46.9 years in the aspiration-assisted MOCA group ($p = 0.893$). The proportion of

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Baseline demographic and clinical characteristics are summarized

Variable	Conventional MOCA (<i>n</i> =110)	Aspiration-assisted MOCA (<i>n</i> =110)	<i>p</i> -value
Age (years)	46.6	46.9	0.893
Male sex, <i>n</i> (%)	51 (46.4%)	54 (49.1%)	0.686
Female sex, <i>n</i> (%)	59 (53.6%)	56 (50.9%)	
CEAP class	2.79	2.76	NS
GSV, <i>n</i> (%)	101 (91.8%)	99 (90.0%)	NS
SSV, <i>n</i> (%)	9 (8.2%)	11 (10.0%)	
Vein diameter (mm)	8.11	7.38	0.005
Sclerosant volume (mL)	7.50	7.47	NS
Baseline CIVIQ-20	35.34	33.49	NS
Baseline VCSS	4.05	3.06	NS

male patients was comparable between groups (46.4% vs. 49.1%, $p = 0.686$). Mean CEAP class was similar in both cohorts (2.79 vs. 2.76). The conventional MOCA group demonstrated a significantly larger preoperative vein diameter than the aspiration-assisted MOCA group (8.11 mm vs. 7.38 mm, $p = 0.005$). Baseline CIVIQ-20 scores were 35.34 and 33.49, while baseline VCSS values were 4.05 and 3.06, respectively (Table 1).

Anatomical and clinical outcomes. At 36 months, anatomical success was achieved in 83 of 110 patients (75.5%) treated with conventional MOCA and in 95 of 110 patients (86.4%) treated with aspiration-assisted MOCA. Overall recanalization occurred in 42 patients (19.1%). Recanalization was observed in 27 patients (24.5%) following conventional MOCA and in 15 patients (13.6%) following aspiration-assisted MOCA. This difference was statistically significant ($p = 0.040$). The absolute risk reduction associated with aspiration-assisted MOCA was 10.9%, corresponding to a relative reduction in recanalization of approximately 44%. Treatment groups demonstrated substantial clinical improvement throughout follow-up. Mean CIVIQ-20 scores improved from 35.34 to 24.11 in the conventional MOCA group and from 33.49 to 22.91 in the aspiration-assisted MOCA group, without a statistically significant between-group difference at 36 months ($p = 0.122$). Mean VCSS decreased from 4.05 to 0.90 following conventional MOCA and from 3.06 to 0.51 following aspiration-assisted MOCA. The aspiration-assisted group demonstrated significantly lower VCSS scores at 36 months ($p = 0.030$). Patient satisfaction was high in both groups, with mean satisfaction scores of 4.85 and 4.87, respectively, ($p = 0.797$) (Table 2).

Complications. The overall incidence of complications was low in both treatment groups. Hematoma or ecchymosis occurred in four patients (3.6%) following conventional MOCA, and in three patients (2.7%) following aspiration-assisted MOCA. Hyperpigmentation was observed in seven patients (6.4%) and

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Clinical and anatomical outcomes at 36 months

Outcome	Conventional MOCA (<i>n</i> =110)	Aspiration-assisted MOCA (<i>n</i> =110)	<i>p</i> -value
Anatomical success, <i>n</i> (%)	83 (75.5%)	95 (86.4%)	0.040
Recanalization, <i>n</i> (%)	27 (24.5%)	15 (13.6%)	0.040
CIVIQ-20 baseline	35.34	33.49	NS
CIVIQ-20 at 36 months	24.11	22.91	0.122
VCSS baseline	4.05	3.06	NS
VCSS at 36 months	0.90	0.51	0.030
Satisfaction score (1–5)	4.85	4.87	0.797
Hematoma / ecchymosis, <i>n</i> (%)	4 (3.6%)	3 (2.7%)	1.000
Hyperpigmentation, <i>n</i> (%)	7 (6.4%)	5 (4.5%)	0.768
Superficial thrombophlebitis, <i>n</i> (%)	4 (3.6%)	2 (1.8%)	0.683
Edema, <i>n</i> (%)	4 (3.6%)	5 (4.5%)	1.000
Paresthesia, <i>n</i> (%)	0	0	1.000
Deep vein thrombosis, <i>n</i> (%)	2 (1.8%)	0	0.498
Pulmonary embolism, <i>n</i> (%)	0	0	1.000

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Association between vein diameter and recanalization

Vein diameter	Patients (<i>n</i>)	Recanalization (<i>n</i>)	Recanalization rate (%)
≤ 8 mm	151	9	6.0
8.1–10 mm	40	17	42.5
10.1–12 mm	23	11	47.8
> 12 mm	6	5	83.3

five patients (4.5%), respectively. Superficial thrombophlebitis occurred in four patients (3.6%) and two patients (1.8%), respectively. Two cases of deep vein thrombosis (1.8%) were recorded in the conventional MOCA group, whereas no cases occurred in the aspiration-assisted MOCA group. No pulmonary embolism was observed during the study period. Preoperative vein diameter demonstrated a strong association with long-term anatomical outcomes (Table 3).

Among veins measuring ≤ 8 mm, recanalization occurred in only 9 of 151 cases (6.0%). In contrast, recanalization was observed in 17 of 40 veins (42.5%) measuring 8.1–10 mm and in 11 of 23 veins (47.8%) measuring 10.1–12 mm. The highest failure rate was recorded in veins larger than 12 mm, where recanalization occurred in 5 of 6 cases (83.3%). To further evaluate the clinical relevance of vein diameter, patients were stratified according to a threshold of 8 mm. Recanalization occurred in 9 of 151 veins (6.0%) measuring ≤ 8 mm compared with 33 of 69 veins (47.8%) measuring > 8 mm. These findings demonstrate a strong relationship between preoperative vein diameter and long-term anatomical durability

following mechanochemical ablation. A multivariate logistic regression model was constructed to identify independent predictors of recanalization at 36 months. Preoperative vein diameter emerged as the strongest independent predictor of recanalization (OR 1.87 per 1-mm increase; 95% CI 1.47–2.38; $p < 0.001$). Male sex was also independently associated with an increased risk of recanalization (OR 2.36; 95% CI 1.03–5.39; $p = 0.042$). Interestingly, this finding has not been consistently reported in the existing literature, and we did not identify previous studies demonstrating a similar association between male sex and an increased likelihood of recanalization. Elderly patients demonstrated a trend toward higher recanalization rates but did not reach statistical significance (OR 1.03 per year; 95% CI 1.00–1.06; $p = 0.058$). Neither CEAP class nor treatment group remained independently associated with recanalization after adjustment for confounding variables.

Discussion. The present study evaluated the long-term outcomes of conventional MOCA and aspiration-assisted MOCA in patients with saphenous vein insufficiency. Two principal findings emerged from this analysis. First, aspiration-assisted MOCA achieved significantly higher anatomical success and lower recanalization rates at 36 months. Second, preoperative vein diameter was strongly associated with long-term outcome and appeared to be one of the most important determinants of treatment durability. Multivariate analysis demonstrated that a vein diameter greater than 6 mm is an independent factor for long-term anatomical success, compared with the treatment technique itself. The anatomical success rate of 86.4% observed following aspiration-assisted MOCA compares favourably with previously published reports on mechanochemical ablation [5–9]. Although MOCA has gained popularity because it avoids thermal injury and tumescent anesthesia, several studies have demonstrated higher recanalization rates compared with endothermal techniques [10–13]. In the present study, recanalization was reduced from 24.5% after conventional MOCA to 13.6% after aspiration-assisted MOCA, representing a relative reduction of approximately 44%. A particularly important finding was the strong relationship between vein diameter and long-term anatomical outcomes. Recanalization increased progressively from 6.0% in veins measuring ≤ 8 mm to 83.3% in veins larger than 12 mm. Furthermore, veins exceeding 8 mm in diameter demonstrated substantially higher recanalization rates than smaller veins. These findings are consistent with previous reports identifying vein diameter as a major predictor of outcome following mechanochemical ablation and other endovenous interventions [6, 7, 11, 13]. Several mechanisms may explain the improved outcomes observed with aspiration-assisted MOCA. Foam sclerosant provides greater endothelial surface coverage than liquid sclerosant and may enhance endothelial injury. In addition, continuous aspiration through the 6F sheath removes a substantial portion of the foam-blood mixture generated during treatment, thereby reducing sclerosant dilution and potentially improving sclerosant-wall contact. Intraoperative duplex ultrasound observations

also suggested reduced migration of foam into the deep venous system, although this observation was not formally quantified. Clinical outcomes were favourable in both treatment groups. Significant improvements were observed in CIVIQ-20 and VCSS scores, while patient satisfaction remained high throughout follow-up. The incidence of complications was low, and no pulmonary embolic events were observed. The present study has several limitations. First, its retrospective single-centre design may introduce selection bias. Second, the aspiration-assisted cohort was treated after the conventional cohort, and therefore a learning-curve effect cannot be completely excluded. Third, baseline vein diameter differed significantly between groups, with larger veins being treated in the conventional MOCA cohort. Finally, the aspiration-assisted cohort differed from the conventional cohort not only by the aspiration maneuver but also by the use of foam rather than liquid sclerosant. Consequently, the individual contribution of aspiration and sclerosant formulation cannot be determined from the present study design. Despite these limitations, the study has several strengths, including a relatively large cohort, complete 36-month duplex ultrasound follow-up, and detailed assessment of both anatomical and clinical outcomes.

Conclusions. Aspiration-assisted foam mechanochemical ablation was associated with lower recanalization rates and improved clinical outcomes compared with conventional mechanochemical ablation during 36-months follow-up. However, preoperative vein diameter emerged as the strongest independent predictor of long-term outcome. Careful patient selection, particularly with respect to vein diameter, appears to be essential for optimizing outcomes following mechanochemical ablation of saphenous vein insufficiency.

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